

REMARKS/ARGUMENTS

Claims 1-58 are pending in the present application. Claims 1-58 were rejected in the Office Action. Claims 1, 19, 21, 32 and 33 have been amended and claims 2, 20, 34, and 47-58 have been canceled. Re-examination and reconsideration of the pending claims as amended are respectfully requested.

Oath/Declaration

The oath/declaration was found to be defective because it did not identify a mailing address for each inventor nor did it identify city and state or foreign country of residence for each inventor. This information was provided on an application data sheet as permitted according to 37 CFR § 1.63 and therefore Applicants believe that the oath/declaration is acceptable.

Claim rejections under 35 U.S.C. § 103

Claims 1-58 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,143,016 to Bleam et al. (hereinafter referred to as Bleam) in view of U.S. Patent No. 5,919,175 to Sirhan (hereinafter referred to as Sirhan) further in view of U.S. Patent No. 4,733,665 to Palmaz (hereinafter referred to as Palmaz).

Without conceding the correctness of the rejections, to expedite prosecution, applicants have amended independent claims 1, 19, and 33 to recite a specific aspect of the invention in which the guidewire tube extends through the tubular prosthesis and/or expandable member, is non-detachably coupled to the catheter shaft, and the guidewire tube is slidable through the exit port in the sheath as the sheath is retracted. Support for these amendments is found at e.g., Figs. 2A-B, paragraph 0014, lines 32 through paragraph 0014, line 1, page 4; and paragraph 0021, lines 16-17, page 5.

Applicant submits that there is no motivation to make the combination suggested by the Examiner. The guidewire replacement device of Sirhan is for use in combination with a

catheter shaft having a proximal guidewire port along its sidewall spaced longitudinally from its distal end, commonly known as a "rapid exchange" catheter design. Sirhan's exchange device has a distal tip designed to seat within the guidewire port in the catheter shaft, allowing the guidewire to be threaded through the tip of the catheter shaft, out the exit port, and through the exchange device. Bleam recognizes that the delivery sheath 28 (carrying stents 12) can be combined with a rapid exchange catheter. The result of that combination is shown in Figs. 11-12 of Bleam. See Bleam at col. 9, lines 7-45. In this device, the guidewire extends entirely through the shortened sheath 28 and exits its proximal end. Given that Bleam has its own rapid exchange design, there is no plausible reason or motivation suggested as to why that design should be switched to that of Sirhan. The cited references disclose two different variations to achieve a rapid exchange catheter, and no advantage of one over the other is disclosed. Thus, no motivation is suggested for combining the rapid exchange device of Sirhan in the device of Bleam as suggested by the Examiner, since Bleam already provides a device for achieving rapid guidewire exchanges.

Moreover, even if a motivation were suggested to make the combination suggested by the Examiner, such a combination fails to disclose or suggest the invention claimed in claims 1, 19 and 33, as amended. First, the claims recite a sheath disposed over a catheter shaft and prosthesis and having an exit port between its proximal and distal ends through which the guidewire tube extends. None of the cited references, taken alone or in combination, disclose or suggest this structure. While it might be argued that Sirhan suggests that a guidewire port could be added to the sidewall of the catheter shaft 83 of Palmaz in order to insert Sirhan's exchange device, neither Sirhan nor any of the cited references discloses or suggests an exit port in the sheath through which a guidewire tube could extend as recited in claim 1. In order for a guidewire to be used with the Palmaz device, the guidewire must not only be pass through the wall of the sheath 89, but through the wall of the catheter shaft 83 as well, so that the wire may then extend through the prosthesis and balloon distally of the catheter. Sirhan fails to teach how a guidewire tube could extend through both an exit port in the sheath and through the prosthesis as claimed. Bleam, on the other hand, teaches that the wire could simply pass through the sheath and into a port in the catheter shaft with no need for a guidewire tube (see, e.g. Fig. 12). In fact,

if a guidewire port were added to both the sheath and the catheter shaft of Palmaz and the exchange device of Sirhan were placed through both ports as apparently suggested by the Examiner, the exchange device would interfere with the retraction of the Palmaz sheath, thus rendering the device inoperable.

Second, claims 1 and 19 as amended recite that the distal extremity of the guidewire tube extends "through the tubular prosthesis...within the sheath." Claim 33 is similarly amended to recite that the distal extremity of the guidewire tube extends "through the expandable member...within the sheath." In Sirhan, the distal tip of the exchange device seats within a guidewire port in the catheter shaft and does not extend through a prosthesis or expandable member as now claimed. Thus, not only does the cited combination fail to disclose or suggest an exit port in a sheath through which a guidewire tube extends, but further fails to disclose or suggest a guidewire tube extending through a tubular prosthesis or expandable member which is disposed within the sheath, as now recited in claims 1 and 33.

In addition, claims 1, 19 and 33 have been amended to recite that the guidewire tube has a distal extremity "non-detachably coupled to the catheter shaft." This structure is not disclosed by Sirhan, in which the exchange device is removable from the guidewire port in the catheter. See, e.g., col. 3, lines 17-23; col. 5, lines 41-65. Sirhan's exchange device is designed specifically to be introduced into the patient separately from the catheter after the catheter has been positioned in a vessel in order to facilitate the exchange of guidewires, after which the exchange device is removed from the patient. Thus, it is necessary that the exchange device of Sirhan be detachable from the catheter shaft. Sirhan's device could not operate for its intended purpose if it were non-detachably coupled to the catheter shaft as now claimed in claims 1, 19 and 33.

Claims 1, 19 and 33 have been further amended to recite that the sheath is "retractable relative [to the catheter shaft] to a retracted position in which the tubular prosthesis is exposed for deployment," and "the guidewire tube slides through the exit port as the sheath is retracted relative to the catheter shaft." While the Examiner might assert that the exchange device of Sirhan could be inserted into a sideport on the sheath of Palmaz, Sirhan fails to disclose or suggest that the exchange device would be slidable through the port relative to the sheath as

the sheath is retracted. Sirhan's device is not utilized during stent deployment, but rather is inserted temporarily to exchange guidewires, then is detached from the catheter and removed. Thus, with the Palmaz device, if Sirhan's exchange device were in place it would be for purposes of exchanging guidewires, during which there is no reason to retract the sheath. Even if the sheath were retracted with Sirhan's exchange device in place, the exchange device would move with the sheath, rather than sliding through the exit port as now claimed. Sirhan fails to disclose any reason for providing such relative axial movement between the exchange device and a sheath or catheter shaft into which it is inserted. In fact, the outer sleeve 13 of Sirhan's device presents an annular rim which would interfere with any substantial movement of the sheath relative to the exchange device.

Because there is no motivation suggested to combine cited references, and because even if combined the cited references fail to teach or suggest all of the claim limitations, *prima facie* obviousness under 35 U.S.C. § 103(a) is not established. Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection and allowance of independent claims 1, 19 and 33 and the claims which depend therefrom.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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